MANUFACTURING AND CHARACTERIZATION SERVICES FOR VACCINES AND OTHER BIOLOGICS FOR INFECTIOUS DISEASES
SBSS-HHS-NIH-NIAID- AI-2017089

Sources Sought Reference Number: SBSS-HHS-NIH-NIAID- AI-2017089

Type of Requirement

☐ New Requirement
☒ Follow-on *(Contract No.:HHSN272201200005I)*
☐ Other (specify):_____

Place of Performance

☒ Place of performance is unknown at this time
☐ Place of performance is known. Address or general location:_____

Recompetition (if applicable)

Advanced Bioscience Laboratories (ABL)
9800 Medical Center Drive
Rockville, MD 20850
800-225-5600

Contracting Office Address

Department of Health and Human Services, National Institutes of Health, National Institutes of Allergy and Infectious Diseases, Office of Acquisitions, 5601 Fishers Lane, MSC 9821, Bethesda, MD, 20892-9821

Sources Sought Notice Information

Introduction

This is a Small Business Sources Sought notice. This is NOT a solicitation for proposals, proposal abstracts, or quotations. The purpose of this notice is to obtain information regarding: (1) the availability and capability of qualified small business sources; (2) whether they are small businesses; HUBZone small businesses; service-disabled, veteran-owned small businesses; 8(a) small businesses; veteran-owned small businesses; woman-owned small businesses; or small disadvantaged businesses; and (3) their size classification relative to the North American Industry Classification System (NAICS) code for the proposed acquisition. Your responses to the information requested will assist the Government in determining the appropriate acquisition method, including whether a set-aside is possible. An organization that is not considered a small business under the applicable NAICS code should not submit a response to this notice.

Background

Research supported by the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), Department of Health and Human Services (DHHS), strives to understand, treat, and ultimately prevent the myriad infectious, immunologic, and allergic diseases that threaten millions of human lives. The NIAID Division of Microbiology and Infectious Diseases (DMID) supports extramural research for the investigation, control and prevention of diseases caused by all infectious agents other than HIV. Support for basic and applied research to develop and evaluate therapeutics, vaccines, and diagnostics is provided through a variety of research grants and contracts. NIAID also supports an array of research resources and services to assist investigators, including programs that provide or make available genomic data and technologies; organisms and state-of-the-art reagents; biocontainment facilities; and preclinical and clinical translational research services (http://www3.niaid.nih.gov/research/resources/dmid).

The development and introduction of new vaccines and biologics against potential agents of bioterrorism, drug-resistant pathogens, emerging and re-emerging infectious diseases, as well as infectious diseases prevalent in resource-limited countries remain a high public health priority. To assist in filling these public health gaps, the NIAID requires a product development-oriented program to provide preclinical development support for multiple vaccine and biologic candidates that emerge from academia, the private sector, or other sources. These services are intended to help a wide variety of investigators in a number of scientific areas obtain critical data needed to acquire additional funding, gain prospective partnerships (either for further development or to support Phase I/II trials), fulfill regulatory requirements, and support Phase I/II clinical studies. While the overall suite of services provided is comprehensive, the intent is to provide individual services on a case-by-case basis for a diverse collection of product candidates, rather than carry a single product candidate through an entire preclinical development pathway.

NIAID anticipates awarding a single IDIQ contract that provides a guaranteed minimum award to the organization or consortium that best meets the overall qualifications needed to fulfill the technical requirements of this solicitation. Sample Task Orders are provided in the RFP solely to evaluate offeror responses and capabilities. Task Orders for specific tasks will be issued after award of the Parent Contract.

Purpose and Objectives

The purpose of this solicitation is to support a suite of services that encompasses the activities commonly associated with product construction, process development, manufacture, and characterization of vaccine and biologic products for infectious diseases. These services will include support of early research and development projects through the product development process and includes manufacture of Phase I/II clinical material of quality sufficient for inclusion in Investigational New Drug (INDs). NIAID recognizes that to obtain the full spectrum of expertise or facilities required to perform all activities set forth in this solicitation, individual organizations will likely need the expertise and resources of other organizations or persons through consortium agreements, partnerships, subcontracts, and/or consultants.

Project requirements

The Contractor shall be prepared to develop a response to individual Task Orders as they are assigned and to specify the methods it will employ in accomplishing the key components of each Task Order.

This IDIQ will be administered and used primarily to support NIAID initiatives that help DMID accomplish its mission, respond to changing priorities as scientific and public health needs shift, rapidly respond to public health emergencies and new disease threats, and improve surge capabilities. The Contractor shall provide NIAID with a broad and flexible range of manufacturing and characterization services for vaccines and other biologics that support preclinical, nonclinical, and clinical studies for promising products when such products emerge from investigator-initiated research studies or other sources identified by NIAID Program staff. The Contractor shall also provide appropriate documentation and support primarily for pre-IND, IND, and BLA submissions. These tasks shall be conducted in accordance with quality oversight that is appropriate to the phase of the specific task and within all applicable and current Federal, state, and local laws, codes, ordinances and regulations, as well as all PHS Safety and Health provisions. These quality regulations at a minimum include current Good Laboratory Practices (GLP) and cGMP [21 CFR Parts -11, -58, -210, -211, -600].

These capabilities may also support vaccines or other biological products that are intended for use in animals that constitute a disease reservoir for, or other disease threat from, a pathogen that has public health significance. Support for efforts associated with zoonotic diseases may be considered on a case-by-case basis dependent on adequate justification for Public Health considerations. In addition, efforts to provide limited support outside of Phase I/II clinical trials may also be considered on a case-by-case basis.

For the purposes of this contract, the following definitions shall apply:

- **Vaccine** – An antigenic preparation used to render an organism immune to an infectious disease by inducing or increasing immunity for prophylaxis and/or therapy, or eliciting immune-based responses that interrupt pathogenesis. Vaccine products include but are not limited to synthetic peptides, recombinant proteins, nucleic acids, viral-like particles, vector-based vaccines, as well as live, modified, and/or attenuated bacteria, viruses, parasites, and other organisms.

- **Vaccine Component** – Any substance or device that maintains, stabilizes, or enhances a vaccine's activity or ability to invoke an immune response. Vaccine components include, but are not limited to, adjuvants to increase immunogenicity, excipients to increase stability, and delivery systems including novel dosage forms and devices.

- **Other Biologic** – Therapeutic preparations made from living organisms or the components of living organisms and are most likely regulated by CBER. Biologics include but are not limited to allergenics; antitoxins; blood and blood products; cellular and gene therapy products. For the purposes of this contract, challenge material for non-clinical, preclinical, and clinical trials will also be included in the definition of biologics. Other biologics will include BSL-2, BSL-3, and BSL-4 material.

- **Reagent** – Materials required to manufacture and test vaccines, vaccine components, and other biologics in support of product release and characterization Reagents include, but are not limited to, assay components such as polyclonal and monoclonal antibodies, receptors, and cell lines; manufacturing reagents such as affinity resins, product specific components such as conjugation reagents, and adjuvant specific reagents; and reagents required for potency, pre-clinical, and non-clinical assays.

The services shall be directed at the following:

- diseases caused by pathogens and toxins on the NIAID Category A, B, and C Priority Pathogens list (http://www.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/research/Pages/CatA.aspx)
- emerging and re-emerging infectious diseases;
- antimicrobial resistant and multi drug resistant infections;
- other bacterial infections;
- fungal infections;
- viral infections; and
- parasitic diseases.

The Contractor shall be required to carry out the Scope and Activities defined in the following five Task Areas. Task Orders may address one Task Area or multiple Task Areas. Institute Contracting Officer's Representative (COR) and designees will collaborate with the Contractor in all awarded Task Orders. Technical Requirements will be defined in the individual Task Areas.

The Technical Requirements have been assembled into the following Task Areas:

Task Area A – Administrative and Technical Management Including Workshops
Task Area B – Product Development Plans and other Feasibility Studies
Task Area C – Product Screening, Optimization, Construction, and Process Development
Task Area D – Product Manufacture under cGMP in Support of Phase I/II Clinical Studies
Task Area E – Quality and Regulatory Management and Support Including Audits

Anticipated period of performance

This is an IDIQ Contract with a seven year ordering period (10 years for Task Area A). The anticipated start date is on/or about May 1, 2018.

Other important considerations

Assume responsibility for the following list of activities which represents a yearly estimate of tasks the Offerors should assume to perform each year under the contract.

Task Area	Title	Estimated No. of Awards/year
A	Administrative and Technical Management Including Workshops	1
B	Product Development Plans and other Feasibility Studies	5
C	Product Screening, Optimization, Construction, and Process Development	4
D	cGMP in Support of Phase I/II Clinical Studies for MCBs	3
	cGMP in Support of Phase I/II Clinical Studies for Bulk Drug Substance and Final Drug Product	1
E	Quality and Regulatory Management and Support Including Audits	2

Assume that the period of performance of task orders may range from one year to multiple years.

Capability statement / information sought

Capability Statements should clearly convey information regarding the respondent's capabilities including: (1) staff expertise, including their availability, experience, and formal and other training; (2) current in-house capability and capacity to perform the work; (3) prior completed projects of similar nature; (4) corporate experience and management capability; and (5) examples of prior completed Government contracts, references, and other related information.

Interested contractors must submit a capability statement describing their company's experience and ability to perform this effort that includes the following: (1) a summary list of similar work previously performed; (2) the professional qualifications and specific experience of staff who may be assigned to the requirement; (3) resumes for proposed key personnel, including the Principal Investigator, that reflect education, and previous work relevant to the proposed requirement; (4) a general description of the facilities and other resources needed to perform the work; (5) demonstrated ability to carry out the work; (6) adequacy of the documented experience with, and appropriateness of plans for: (a) receiving, formatting, storing and shipping compounds and biological agents; (b) technology transfer processes; (c) shipping, handling and storing of reagents and formulated vaccine and biologic products, and highly infectious Select Agents; (d) shipping, handling and storing of highly infectious Select Agents; (e) experience working with potential biohazards, toxic chemicals, and radioisotopes; and (f) adequacy of the plan for training, implementation, and monitoring of safety procedures; (7) availability of adequate facilities, equipment, and resources with sufficient capacity necessary to safely and efficiently accomplish the work described in the Statement of Work in a timely manner, to include documented access to BSL-2, BSL-3, and BSL-4 facilities; (8) perform work in accordance with the following guidelines: "Biosafety in Microbiological and Biomedical Laboratories", Centers for Disease Control and Prevention and the National Institutes of Health, Fifth Edition 2007 (http://www.cdc.gov/biosafety/publications/bmbl5/index.htm); Federal Guidelines for Research involving Recombinant DNA molecules at http://oba.od.nih.gov/rdna/nih_guidelines_oba.html);and Recommendations for the Safe Handling of Cytotoxic Drugs, NIH Publication No. 92-2621 and the NIH Guidelines for the Laboratory Use of Chemical Carcinogens, NIH Publication No. 81-2385.

Page Limitations:

Interested qualified small business organizations should submit a tailored Capability Statement not to exceed five pages, excluding resumes. Capability Statements must not include links to internet web site addresses (URLs) or otherwise direct readers to alternate sources of information. Font size must be 10 to 12 points. Spacing must be no more than 15 characters per inch. Within a vertical inch, there must be no more than six lines of text. Print margins must be at least one-inch on each edge of the paper. Print setup should be single-sided on standard letter size paper (8.5 x 11" in the U.S., A4 in Europe). All proprietary information should be marked as such.

Required Business Information:

- DUNS.
- Company Name.
- Company Address.
- Company Point of Contact, Phone and Email address
- Current GSA Schedules and/or Government-wide Acquisition Contracts (GWACs) appropriate to this Sources Sought.
- Do you have a Government approved accounting system? If so, please identify the agency that approved the system.
- Type of Company (i.e., small business, 8(a), woman owned, veteran owned, etc.) as validated via the System for Award Management (SAM) located at https://www.sam.gov/index.html/#1. This indication should be clearly marked on the first page of your Capability Statement (preferable placed under the eligible small business concern's name and address).

Number of Copies:

Please submit one (1) electric copy of your response as follows:

All Capability Statements sent in response to this Small Business Sources Sought notice must be submitted electronically (via e-mail) to Lauren Tipton, Contract Specialist, at lauren.tipton@nih.gov in MS Word or Adobe Portable Document Format (PDF). The e-mail subject line must specify SBSS-HHS-NIH-NIAID- AI-2017089. Facsimile responses will not be accepted.

Common Cut-off Date:

Electronically submitted tailored capability statements are due no later than 12:00 PM (Eastern Prevailing Time) on 12/05/2016. ***CAPABILITY STATEMENTS RECEIVED AFTER THIS DATE AND TIME WILL NOT BE CONSIDERED.***

Disclaimer and Important Notes

This notice does not obligate the Government to award an IDIQ contract or Task Order or otherwise pay for the information provided in response. The Government reserves the right to use information provided by respondents for any purpose deemed necessary and legally appropriate. Any organization responding to this notice should ensure that its response is complete and sufficiently detailed to allow the Government to determine the organization's qualifications to perform the work. Respondents are advised that the Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted. After a review of the responses received, a pre-solicitation synopsis and solicitation may be published in Federal Business Opportunities. However, responses to this notice will not be considered adequate responses to a solicitation.

Confidentiality

No proprietary, classified, confidential, or sensitive information should be included in your response. The Government reserves the right to use any non-proprietary technical information in any resultant solicitation(s)."